REMARKS

Claims 1-7, 24 and 49-56 are pending in this application. Claims 8, 12-23 and 25-48 have been previously cancelled without prejudice to the filing one or more divisional applications. Claim 1 is amended to more particularly point out and distinctly define that which Applicant regards as the invention. In particular, Claim 1 is amended herein to add the word "consisting" before the formula of the peptide.

The amendment to Claim 1 is formal in nature and does not constitute new matter as defined under 35 U. S. C. § 132. Applicant respectfully requests entry of the amendment.

I. INTERVIEW WITH THE EXAMINER

Applicant would like to extend his gratitude for the interview graciously granted by Examiners Low and Robinson to the Applicant's attorney. In the interview, it was discussed whether the transitional word "comprising" in the preamble of Claim 1 causes the formula X_1-SEQ ID NO:1-X_2 in Claim 1 to read on human kininogen peptides having a sequence outside the constraints of that formula.

While the Examiners acknowledged that the pharmaceutical composition claimed can contain other active or inactive ingredients therein, it was the Examiners' position that the language "comprising" in the preamble of Claim 1 opens the scope of the X_1-SEQ ID NO:1-X_2 formula to embrace peptides outside the formula. To this end, the Examiners suggested addition of the word "consisting" before formula X_1-SEQ ID NO:1-X_2 in Claim 1 in order to clarify that the peptides of formula X_1-SEQ ID NO:1-X_2 1 are indeed fixed size peptides (*i.e.*, no less than 8 and no more than 32 amino acids long). The Examiners suggested that such an amendment would overcome the art rejections of record against currently pending claims.

Without acquiescing in the propriety of the Examiners proposed amendments, and solely to advance prosecution of this case, Applicant has amended Claim 1 to add the word "consisting" before the formula X_1-SEQ ID NO:1-X_2.

II. REJECTION OF CLAIMS UNDER 35 U. S. C. § 102 OVER AUERSWALD

The Examiner rejects Claims 1-7 under 35 U. S. C. § 102 as allegedly being anticipated by Auerswald *et al* ("Auerswald"). The rejection alleges that Auerswald teaches the sequences contained in SEQ ID NOS: 1-4, 9 and 10. The rejection further alleges that although the sequences disclosed by Auerswald exceed 12 amino acid residues, the claims recite open ended languages such as "comprising" and "has". Thus, the rejection concludes that the reference sequence is identical to the claimed sequences. Applicant respectfully traverses the rejection.

Without acquiescing in the propriety of the Examiner's rejection, and solely to advance prosecution of this case, Applicant has amended Claim 1 to add the word "consisting" before the formula X_1-SEQ ID NO:1-X_2.

Applicant respectfully submits that Auerswald does not disclose the pharmaceutical composition claimed. Contrary to the Examiner's contentions, Auerswald does not disclose the peptides of Claim 1. The word "has" does not appear in Claim 1. For the reasons discussed below, the word "comprising" in the preamble of Claim 1 does not cause the formula X1-SEQ ID NO:1-X2 to read on human kininogen (HK) peptides outside the scope of the formula.

Auerswald discloses a 125-amino acid peptide corresponding to a HK peptide, which is designated as "ANSM kininogen" and includes the entire HK domain 3. Moreover, the ANSM peptide of Auerswald is about four times larger than the maximum length associated with the claimed peptide.

As it is evident from the language of Claim 1, the transitional word "comprising" links different components of the claimed composition and clearly defines the scope of the pharmaceutical composition with respect to the elements such as a pharmaceutically acceptable

carrier, and other active[1] or inactive ingredients that may be included in the pharmaceutical composition. The word "comprising" does not open the scope of the formula in Claim 1.

Indeed, as it is amply evident from a reading of Claim 1, the peptide of the pharmaceutical composition claimed is of a fixed length (8 to 32 amino acid long) and a has specific formula of X_1-SEQ ID NO: 1-X_2, wherein X_1 and X_2 are each from zero to twelve amino acids. SEQ ID NO: 1 is: Asn-Asn-Ala-Thr-Phe-Tyr-Phe-Lys, which sequence corresponds to a portion of the HK domain 3. Assuming that X_1 and X_2 are each zero to twelve amino acids flanking SEQ ID NO: 1, the shortest claimed peptide is 8 amino acids long, and the largest claimed peptide is 32-amino acids long. Auerswald does not disclose such peptides. Accordingly, Auerswald does not anticipate the claimed invention.

Claims 2-7 recite additional features of the claimed pharmaceutical composition. Since Claim 1 is not anticipated by Auerswald, Claims 2-7 are likewise novel.

Reconsideration and withdrawal of this rejection is respectfully requested

III. REJECTION OF CLAIMS UNDER 35 U. S. C. § 103 OVER AUERSWALD

The Examiner rejects Claims 1-7, 24, and 49-56 as being allegedly obvious over Auerswald. Specifically, the Examiner contends that Auerswald teaches the claimed peptides with a 100% sequence identity which are described in the instant specification as possessing anti-angiogenic activity. While Claims 1-7 are included in the Examiner's rejection, the reasons given for obviousness are focused on a method of inhibiting angiogenesis, which is the invention of Claims 24, and 49-56. Applicant respectfully traverses this rejection.

[1] Of course, the other active ingredient may be a kininogen peptide *outside* the scope of the formula of Claim 1, the novelty of the claim being satisfied by the requirement that the composition contains at least one peptide *within* the bounds of the formula.

Applicant respectfully submits that, for the reasons stated under Section II above, Auerswald does not disclose the pharmaceutical composition of the claimed invention. Furthermore, contrary to the Examiner's contention, there is no teaching or disclosure in Auerswald, other than the impermissible hindsight gleaned from the invention itself, that the peptides disclosed in Auerswald have anti-angiogenic activity.

Auerswald does not teach or suggest that HK has anti-angiogenic activity. Neither does Auerswald disclose a pharmaceutical composition comprising ANSM kininogen or a pharmaceutical utility for ANSM kininogen. Therefore, it would not have been obvious to one of ordinary skill in the art, at the time the invention was made, to combine ANSM kininogen with a pharmaceutically acceptable carrier, less so to make a pharmaceutical composition to treat angiogenesis. Auerswald provides no inventive or motivation for preparing a pharmaceutical composition of ANSM kininogen to inhibit angiogenesis.

Moreover, assuming *arguendo*, which is not admitted, that one of ordinary skill in the art would be motivated to combine ANSM kininogen with a pharmaceutically acceptable carrier, the result would not be the claimed invention because, for the aforementioned reasons, ANSM kininogen is not a peptide within the formula X_1-SEQ ID NO:1-X_2.

Accordingly, the pharmaceutical composition of Claims 1-7 and the method of Claim 24, and 49-56 would not have been obvious to one of ordinary skill in the art at the time the invention was made in view of the disclosure of Auerswald.

Reconsideration and withdrawal of this rejection is respectfully requested.

IV. REJECTION OF CLAIMS UNDER 35 U.S.C. § 103 OVER AUERSWALD IN VIEW OF COLMAN

The Examiner rejects Claims 1-7, 24, and 49-56 as allegedly being obvious over Auerswald in view of Colman. While the Examiner notes that Colman does not teach the

peptides of formula X_1-SEQ ID NO: 1-X_2, it is the Examiner's position that Colman teaches "the same domain as claimed". Applicant respectfully traverses this rejection.

The Examiner's reasons for rejection of claims over Auerswald is the same as stated under Sections II and III above, Applicant's arguments against those rejections equally apply to this rejection.

With respect to the rejection over Colman, Applicant respectfully submits that Colman does not cure the deficiency of Auerswald with respect to the claimed invention because Colman does not disclose the peptides of formula X_1-SEQ ID NO:1-X_2 as claimed. Claims 1-7 are directed to a pharmaceutical composition comprising peptides of domain 3 of HK (*i.e.*, amino acids Gly(235)-Met(357)) having a specific formula. Colman does not disclose the peptides of domain 3 of HK. Rather, Colman's peptides are derived from domain 5 of HK (*i.e.*, amino acids Lys(420)-Ser(513)). The two domains are entirely distinct and cover non-overlapping regions of the kininogen molecule.

Accordingly, the combination of Auerswald and Colman, even if properly made, which is not admitted, does not render the subject matter of Claims 1-7, 24 and 49-56 obvious.

Withdrawal and reconsideration of this rejection is respectfully requested.

CONCLUSION

In light of the above, Applicant respectfully submits that all pending claims are allowable over the art of record, and a Notice of Allowance is courteously solicited. The foregoing is submitted as a full and complete response to the Office Action dated August 8, 2003.

The Examiner is invited and encouraged to contact the undersigned attorney of record if such contact will facilitate an efficient examination and allowance of the application.

Respectfully submitted,

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